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PTO/SB/21 (04-07)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

| | |
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| Application Number | 10/522,351 |
| Filing Date | January 26, 2005 |
| First Named Inventor | Bruce J. Simon |
| Art Unit | 1651 |
| Examiner Name | Susan Emily Fernandez |
| Attorney Docket Number | 5490E-000292/NPB |

Total Number of Pages in This Submission

ENCLOSURES (check all that apply)

| | | |
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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form HDP 1449; 23 articles; return postcard |
|---|--|--|

Remarks

The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|----------------------------------|----------|--------|
| Firm Name | Harness, Dickey & Pierce, P.L.C. | | |
| Signature | | | |
| Printed name | David L. Suter | | |
| Date | May 11, 2007 | Reg. No. | 30,692 |

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| Signature | | Date | May 11, 2007 |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EV 755 416 470 US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/522,351
Filing Date: January 26, 2005
Applicant: Bruce J. Simon
Group Art Unit: 1651
Examiner: Susan Emily Fernandez
Title: METHODS AND COMPOSITIONS FOR TREATING TISSUE DEFECTS USING PULSED ELECTROMAGNETIC FIELD STIMULUS
Attorney Docket: 5490E-000292/NPB
EBI 0891 (E-120)

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. **COPIES**

A. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated

October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☐ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☐ English translations are provided:

3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☐ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.

Filing Date

Inventor(s)

V. THIS IDS IS BEING FILED UNDER

A. ☒ **37 C.F.R. § 1.97(b):** (check only one box)

1. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. ☒ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☐ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ **37 C.F.R. § 1.97(d):**

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box, if applicable)

A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-identified fee. A duplicate copy of this paper is attached.


Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

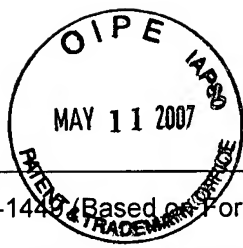
Respectfully submitted,

Dated: May 11, 2007

By: 
David L. Suter
Reg. No. 30,692

Harness, Dickey & Pierce, P.L.C.
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Bloomfield Hills, Michigan 48303
(248) 641-1600

DLS/kq



FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Sheet 1 of 2

ATTORNEY DOCKET NO.

5490E-000292/NPB
EBI 0891 (E-120)

SERIAL NO.

10/522,351

APPLICANT

Bruce J. Simon

FILING DATE

January 26, 2005

GROUP

1651

U.S. PATENT DOCUMENTS

| Ref. Desig. | Examiner's Initials | Document Number | Date | Name | Class/ Subclass | (If appropriate) Filing Date |
|-------------|---------------------|-----------------|------------|----------------|-----------------|------------------------------|
| 1. | | 2005/0049640 | 03/03/2005 | Gurtner et al. | | |

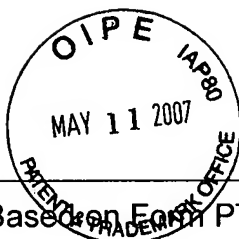
OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

| Ref. Desig. | Examiner's Initials | |
|-------------|---------------------|---|
| 1. | | Amaral et al., Angiogenesis induced by electrical stimulation is mediated by angiotensin II and VEGF, Microcirculation 8, 57-67 (2001). |
| 2. | | Anderson et al., Electrical properties of wet collagen, Nature 218, 166-168 (1968). |
| 3. | | Bassett et al., Electrical behavior of cartilage during loading, Science 178, 982-983 (1972). |
| 4. | | Bassett et al., Generation of electric potentials by bone in response to mechanical stress, Science 137, 1063-1064 (1962). |
| 5. | | Bassett, The development and application of pulsed electromagnetic fields (PEMFs) for ununited fractures and arthrodeses, Orthop Clin North Am 15, 61-87 (1984). |
| 6. | | Becker et al., Bioelectric effects in tissue, Clin Orthop 43, 251-253 (1965). |
| 7. | | Borgens, Endogenous ionic currents traverse intact and damaged bone, Science 225, 478-482 (1984). |
| 8. | | Carmeliet et al., The emerging role of the bone marrow-derived stem cells in (therapeutic) angiogenesis, Thromb Haemost 86, 289-297 (2001). |
| 9. | | Chekanov et al., Angiogenesis in the latissimus dorsi muscle using different regimens of electrical stimulation and pharmaceutical support, Asaio J 46, 305-312 (2000). |
| 10. | | Cuevas et al., Electromagnetic therapeutic angiogenesis: the next step, Neurol Res 22, 349-350 (2000). |
| 11. | | Egginton et al., Selective long-term electrical stimulation of fast glycolytic fibres increases capillary supply but not oxidative enzyme activity in rat skeletal muscles, Exp Physiol 85.5, 567-574 (2000). |
| 12. | | Isner, Myocardial gene therapy, Nature 415, 234-239 (2002). |
| 13. | | Kalka et al., Transplantation of ex vivo expanded endothelial progenitor cells for therapeutic neovascularization, Proc Natl Acad Sci USA 97(7), 3422-3427 (2000). |
| 14. | | Kamihata et al., Implantation of bone marrow mononuclear cells into ischemic myocardium enhances collateral perfusion and regional function via side supply of angioblasts, angiogenic ligands, and cytokines, Circulation 104, 1046-1052 (2001). |

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 2 of 2

ATTORNEY DOCKET NO.

5490E-000292/NPB
EBI 0891 (E-120)

SERIAL NO.

10/522,351

APPLICANT

Bruce J. Simon

FILING DATE

January 26, 2005

GROUP

1651

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

| Ref. Desig. | Examiner's Initials | |
|-------------|---------------------|--|
| 15. | | Kanno et al., Establishment of a simple and practical procedure applicable to therapeutic angiogenesis, Circulation 99, 2682-2687 (1999). |
| 16. | | Linderman et al., Development of an implantable muscle stimulator: measurement of stimulated angiogenesis and poststimulus vessel regression, Microcirculation 7, 119-128 (2000). |
| 17. | | Lotke et al., Electromechanical properties in human articular cartilage, J Bone Joint Surg Am 56-A(5), 1040-1046 (1974). |
| 18. | | Nehls et al., A novel, microcarrier-based in vitro assay for rapid and reliable quantification of three-dimensional cell migration and angiogenesis, Microvasc Res 50, 311-322 (1995). |
| 19. | | Shamos et al., Bioelectric effects in tissue, Clin Orthop 43, 254-255 (1965). |
| 20. | | Shamos et al., Physical bases for bioelectric effects in mineralized tissues, Clin Orthop Relat Res 35, 177-188 (1964). |
| 21. | | Sharrard et al., The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation, J Bone Joint Surg 64-B(2), 189-193 (1982). |
| 22. | | Sharrard, A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures, J Bone Joint Surg Br 72, 347-355 (1990). |
| 23. | | Tomanek et al., Angiogenesis: new insights and therapeutic potential, Anat Rec 261, 126-135 (2000). |

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Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.